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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,541

12/05/2003

D. Bruce Modesitt

16497.138.2

1905

57360

7590

09/23/2008

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/729,541	MODESITT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-18 and 20-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Andreas et al. (6,036,699). Andreas et al. disclose, at least in figures 1-2B and 4-8 and in col. 9, line 44 to col. 11, line 43; a device and a method with the device for closing an opening (A) in a tissue or blood vessel, where the device and method include a shaft (440) having a proximal end portion and a distal end portion, a foot (a tubular element (unlabeled) attached to element 406 and internal to element 426 as seen in figs. 2A and 2b or 404 with respect to claims 2 and 6) disposed on the distal end of the shaft that is spaced apart from the proximal end portion and is movable with respect to the shaft, a foot receptacle (402, 426, or a tubular element (unlabeled) attached to element 406 and internal to element 426 as seen in figs. 2A and 2b with respect to claims 2 and 6) disposed at the distal end portion of the shaft and at least a portion of the foot receptacle (402) passing through the shaft (440); a flexible guidebody (442 or 426 with respect to claims 2 and 6) coupled to the distal end portion of the shaft and

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extending beyond the foot receptacle and defining a guidewire (442) lumen (within 404 or 426) or a suture storage lumen (within 426), where the foot (404) is movable from within the foot receptacle (426) to a deployed position with the foot extending laterally from the shaft (440) across the distal end portion of the shaft (i.e., a portion of the foot is positioned transverse to the distal end of the shaft as the foot is curved laterally), where the flexible guide body (426) defines a guidewire entry port at its distal end (an opening at the distal end of element 426) and an exit port proximal to the entry port (an opening at the proximal end of element 426), where the exit port is situated at a location distal to the distal end of the shaft (402), where a portion of the shaft (404) curves such that the flexible guide body extends from the shaft (402) at an angle relative to an axis of the shaft, where the device includes a length of suture (422) supported by the foot, where the flexible guidebody (426) defines a lumen with the suture extending therethrough, where a needle (410) is advanceable from the shaft through tissue and to the foot when the foot is moved to deployed position (i.e., the needle is movable distally to the foot (retractable--according to col. 10, lines 24-31)), where the method includes partially withdrawing the flexible guidebody (404 or 426) from a tissue opening to reduce a flow of blood through the opening (see col. 11 lines 11-14); where the method includes moving the foot from a parked position to a deployed position (see figs. 1 and 4), forming a needle path from the shaft through the tissue (the path extending from needle lumen 420 to guide channel 408), advancing suture along the needle path, securing a suture loop to close the opening (see fig. 8), and fully withdrawing the flexible guidebody from the opening after the loop is at least partially secured (see fig. 6); where the

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opening is accessed through subcutaneous tissue; where the flexible guidebody (404) extends from the shaft at an angle relative to an axis of the shaft (402) and positioned coaxially within the blood vessel, while the shaft is positioned coaxially within a tissue tract, and where the foot is aligned with the blood vessel when in the deployed position.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 38, 40, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al. (5,374,275) in view of Klein et al. (6,517,553). Bradley et al. disclose the invention substantially as claimed. Bradley et al. disclose, at least in figures 2, 6, and 7; a device for closing an opening in tissue, where the device includes a shaft (12) having a proximal end portion, a distal end portion, a foot receptacle (66), and a least one pin spaced from the proximal end portion (unlabeled pin connected to elements 72 and 24); a foot (28) having at least one slot (at interface with 72) or with respect to claims 43-45, the combination of 72, 74 and 28; the at least one slot being connected to at least one pin at the distal end portion of the shaft, and the foot being movable with respect to the shaft; and a guidebody extending from the distal end portion of the shaft (the conical tip of the shaft as seen in figures 6 and 7), where the foot is rotationally movable about the at least one pin, where the foot has at least one receptacle (28 with respect to claims 43-45) with a slot oriented with respect to a

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surface of the at least one receptacle, and where the slot extends substantially tangential to the surface of the at least one receptacle and extends laterally through (i.e., the side of) the foot. However, Bradley et al. do not disclose that the guidebody is flexible and is configured to receive a guidewire. Klein et al. teach, at least in figures 4A and 8 and col. 8, lines 49-55 and col. 10, line 65 to col. 11, line 2; a device for closing an opening in tissue, where the device includes a flexible guidebody (66) configured to receive a guidewire. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Klein et al., to modify the guidebody of Bradley et al., so that it is flexible and configured to receive a guidewire. Such modifications would allow the device of Bradley et al. to penetrate into and be guided through a hollow organ, such as a blood vessel, without tearing the penetration and without damaging the inner wall of the organ. An opening in the hollow organ can then be closed with the device of Bradley et al.

5. Claims 38, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (5,368,601) in view of Klein et al. (6,517,553). Sauer et al. disclose the invention substantially as claimed. Sauer et al. disclose, at least in figures 1-5; a device for closing an opening in tissue, where the device includes a shaft (12) having a proximal end portion, a distal end portion, a foot (70 or 72) having at least one slot (82 or 84); the at least one slot being connected to at least one pin (56, 58 or 98 via suture 94) at the distal end portion of the shaft, and the foot being movable with respect to the shaft; where the slot is axially movable with respect to the at least one pin, where the shaft has a foot receptacle (50 or 52), and where the foot is slidingly

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received within the receptacle. However, Sauer et al. do not disclose a flexible guidebody configured to receive a guidewire that extends from the distal end of the shaft. Klein et al. teach, at least in figures 4A and 8 and col. 8, lines 49-55 and col. 10, line 65 to col. 11, line 2; a device for closing an opening in tissue, where the device includes a flexible guidebody (66) configured to receive a guidewire and extending from the distal end of a shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Klein et al., to modify the shaft of Sauer et al., so that it includes a flexible guidebody configured to receive a guidewire. Such modifications would allow the device of Sauer et al. to penetrate into and be guided through a hollow organ, such as a blood vessel, without tearing the penetration and without damaging the inner wall of the organ. An opening in the hollow organ can then be closed with the device of Sauer et al.

### ***Response to Amendment***

6. Applicant's arguments filed on June 9, 2008 and regarding the rejection based on the Andreas reference have been fully considered but they are not persuasive: See the rejection above. That is, Andreas indeed discloses a foot (404) extending laterally across the distal end portion of the shaft (440), when the foot is bent and crosses in front of or distally of the shaft. With respect to arguments regarding the rejection of claims 38-45: The arguments are moot, because of new grounds of rejection. The rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is hereby withdrawn.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

September 23, 2008